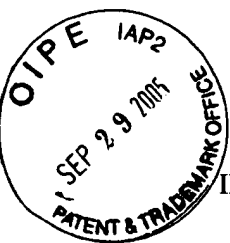


Application No.: 09/745,751  
Amendment Rule 111 dated September 29, 2005  
Reply to Office Action dated June 29, 2005  
Attorney Docket No.: 3486-018

## **EXHIBIT E**

**Haruhisa FUKAYAMA, DDS, PhD, JBDA, IJBDA**



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/745,751 Confirmation No.: 1104  
Applicant : HOCHMAN, Mark N.  
Filed : December 21, 2000  
TC/A.U. : 3763  
Examiner : HAYES, Michael J.  
  
Docket No. : 3486-018  
Customer No. : 22440

DECLARATION UNDER 37CFR 1.132

I, Haruhisa Fukayama, DDS, PhD, JBDA, IJBDA, hereby make the following declaration in support of the above-named application:

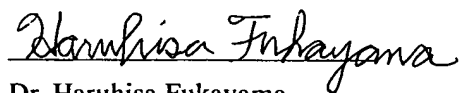
1. I reside at Naritahigashi 5-5-2, Suginami, Tokyo, 166-0015, Japan .
2. I am a licensed dentist and I have been practicing Dentistry for 24 years.
3. I have written and published many articles in the field of dentistry, including articles related to sedation in dentistry and local anesthesia. I have also reviewed many articles in this field and I am frequent lecturer, having made presentations all over the world.
4. A copy of current Curriculum Vitae is attached providing more details of my background and expertise in the field of dentistry.
5. One problem in the field of dentistry and more particularly, during the injection of an anesthetic into a living tissue prior to performing dental procedures pertains to needle bending. As a needle is introduced through tissues to a preselected site for delivering an anesthetic, it frequently bends. This action causes discomfort in the patient and pain. In many instances, a patient either stiffens up, or, worse, tries to move involuntary away from the needle, or close his mouth, thereby causing even more discomfort.
6. Recently, Dr. Mark Hochman disclosed to me his invention, that solves the problem of

needle bending. More specifically, Dr. Hochman has disclosed to me:  
a method of injecting a drug into a patient through a needle having a lumen comprising the steps  
of: advancing said needle into the tissue linearly along a longitudinal axis of the needle;  
simultaneously rotating the needle along its longitudinal axis to reduce deflection of the needle;  
and injecting the drug.

7. Initially, I had some doubts that this procedure would work. However, I have tried this technique at least 100 times on patients and I found that it is very effective in reducing needle bending and, subsequently, in reducing or eliminating patient discomfort and pain.

8. I found that for the procedure was effective as long as I kept the needle rotating to change the orientation of the bevel of the needle in somewhat continuous manner during the insertion, and that the total angle of rotation of the needle, or whether it was rotated only in a single direction, or back and forth, did not matter that much. I found that it was very easy for me to determine intuitively how much to rotate the needle from the reaction of the patient. More particularly, if I did not rotate the needle enough to prevent it from bending, the patient became uncomfortable as indicated by his body language and other indicia, including verbal communication from the patient. Because of this immediate voluntary or involuntary feedback from the patient, it was very easy to adjust the procedure to each patient as required.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Dr. Haruhisa Fukayama

Date: 09/02/2005

## Curriculum Vitae

Haruhisa Fukayama, DDS, PhD, JBDA, IJBDA

Date of Birth: May 15<sup>th</sup>, 1954.

Place of Birth: Tokyo, Japan.

### 1. University educations;

*Doctoral education:* Department of Anesthesiology, Faculty of Dentistry, Tokyo Medical and Dental University, Tokyo Japan 1981-1985

*Undergraduate education:* Faculty of Dentistry, Tokyo Medical and Dental University, Tokyo, Japan 1975-1981

### 2. Academic appointments;

Instructor, Department of Anesthesiology, Faculty of Dentistry, Tokyo Medical and Dental University: *April 1985 – March 1986*

Assistant Professor, Department of Anesthesiology, Faculty of Dentistry, Tokyo Medical and Dental University: *April 1986 – March 1989*

Research fellow, Hospital Dentistry, School of Dentistry, UCLA: *April 1989 – September 1991*

Assistant Professor, Department of Anesthesiology, Faculty of Dentistry, Tokyo Medical and Dental University: *October 1991 – March 1998*

Lecturer, Department of Anesthesiology, Faculty of Dentistry, Tokyo Medical and Dental University: *April 1998 – March 1999*

Associate Professor, Anesthesiology and Clinical Physiology, Department of Oral Restitution, Division of Oral Health Sciences, Graduate School, Tokyo Medical and Dental University: *April 1999 – March 2004*

Professor, Dental Anesthesiology, School of Dental Medicine, Tsurumi University: *April 2004 – present*

### 3. Professional organizations;

Japanese Dental Society of Anesthesiology

Japan Society of Anesthesiology

Japanese Society of Oral and Maxillofacial Surgeons

The Stomatological Society, Japan

The Japanese Association for Dental Science

International Federation of Dental Anesthesiology Societies

Japanese Society of Gerodontology

Japanese Dental Education Association

The Japanese Society for Disability and Oral Health

Japanese Society of Dentistry for Medically Compromised Patient

### 4. Board Certification and/or Licensure;

Doctor of Dental Surgery: Nr. 83797 (1981), Ministry of Health and Welfare, Japan

Doctor of Dental Science (PhD): Nr. 513 (1985), Tokyo Medical and Dental University

Japanese Board of Dental Anesthesia (JBDA): Nr. 260 (1986), Japanese Dental Society of Anesthesiology

Instructor of Japanese Board of Dental Anesthesia (IJBDA): Nr. 44 (1994), Japanese Dental Society of Anesthesiology

### 5. Work address:

Department of Dental Anesthesiology, School of Dental Medicine, Tsurumi University.

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